DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 16, 2015

Fukuda Denshi USA, Inc.
Doug Blakely
Director- Regulatory Affairs
17725 NE 65th St, Building C
Redmond, Washington 98052

Re: K150030
Trade/Device Name: Fukuda Denshi Dynascope Model DS-8000 Series Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, BZK, DQA, CCK, MWI
Dated: January 12, 2015
Received: January 15, 2015

Dear Doug Blakely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K150030**

Device Name: **Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)**

Indications For Use:

The Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor provides a simple and reliable method to display and document the continuous hemodynamic, cardiovascular observations that are typically required of critically ill patients. The target populations of the system are adult, pediatric, and neonatal patients, who may be located in a hospitals ICU, CCU, OR, ER, recovery or other critical care area, with the exception of the ST segment, arrhythmia analysis, and SpHb for which the target populations are adult and pediatric only excluding neonates. The DS-8000 Series monitor can also be used to follow patients whose treatment requires close observation of specific physiological parameters. These patients may be in a clinic or other healthcare environment under the care of a physician.

The availability of DS-LAN connection, through either a built in Ethernet LAN or external telemetry transmitter, allows remote monitoring when combined with Fukuda Denshi Central Station Monitors.

Parameters such as ECG, heart rate, respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO_2), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb), plethysmograph, temperature, invasive blood pressure (IBP), cardiac output, carbon dioxide concentration (CO_2), nitrous oxide concentration (N_2O), oxygen concentration (O_2), anesthetic agent concentration (AG), and Spirometry may be monitored individually or in any grouping required by the clinician.

The Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor is not recommended for home use, when it has not been ordered by a physician.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 870.92.

The assigned 510(k) number is: **K150030** .

Submitter: Fukuda Denshi USA, Inc.
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- Contact Person: Doug Blakely
  Director- Regulatory Affairs
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- Date Prepared: June 18, 2013

Device Name:

- **Proprietary Name:** Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)
- **Common Name:** Patient Monitor
- **Product Code:** MHX – Monitor, Physiological, Patient (with arrhythmia detection or alarms)
- **Regulation Number:** 21 CFR Part 870.1025
- **Device Class:** II
- **Review Panel:** Cardiovascular

510(k) Summary
Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)

- Subsequent Product Code:

510(k) K#	Product Code	Regulation Number	Classification Name	Panel
K964187	DSI	870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm).	Cardiovascular
K083697	BZQ	868.2375	Breathing frequency monitor	Anesthesiology
	CCK	868.1400	Carbon Dioxide Gas Analyzer	Anesthesiology
	DQA	870.2700	Oximeter	Anesthesiology
	DRT	870.2300	Cardiac monitor (including cardiotachometer and rate alarm).	Cardiovascular
	DSK	870.1110	Blood Pressure Computer	Cardiovascular
	DXN	870.1130	Non-Invasive Blood Pressure Measurement System	Cardiovascular
	FLL	880.2910	Clinical electronic thermometer.	General Hospital
K062754	BZK	868.1850	Monitoring spirometer	Anesthesiology
	CBS	868.1620	Halothane gas analyzer	Anesthesiology
K981066	DPS	870.2340	Electrocardiograph	Cardiovascular
K021090	DQA	870.2700	Oximeter	Anesthesiology
K100428	DQA	870.2700	Oximeter	Anesthesiology
K094012	CCK	868.1400	Carbon Dioxide Gas Analyzer	Anesthesiology
K042601	CCK	868.1400	Carbon Dioxide Gas Analyzer	Anesthesiology
K053234	MWI	870.2300	Cardiac Monitor (including cardiotachometer and rate alarm)	Cardiovascular
	DXN	870.1130	Non-Invasive Blood Pressure Measurement System	Cardiovascular
	DSK	870.1110	Blood Pressure Computer	Cardiovascular
	FLL	880.2910	Clinical electronic thermometer.	General Hospital

510(k) Summary
Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)

	DQA	870.2700	Oximeter	Anesthesiology
	CCK	868.1400	Carbon Dioxide Gas Analyzer	Anesthesiology
	CBQ	868.1500	Enflurane gas analyzer	Anesthesiology
	CBS	868.1620	Halothane gas analyzer	Anesthesiology
	CBR	868.1700	Nitrous Oxide gas analyzer	Anesthesiology
	CCL	868.1720	Oxygen gas analyzer	Anesthesiology

Legally Marketed Device:

Fukuda Denshi DynaScope Model DS-5300 Patient Monitor, 510(k) # **K964187**
Fukuda Denshi DynaScope Model DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M), 510(k) # **K083697**
Datascope model "Gas Module SE", 510(k) # **K062754** (for Spirometry portion)

In addition, several functions of the DS-8000 Series Patient Monitor utilize technology incorporated into previously cleared devices and several OEM manufactured modules that have received separate clearance from the FDA as follows:

The 12-Lead ECG analysis software module used in the DS-8000 Series is the same as that used in the Fukuda Denshi CardioMax model FX-4010 Multi Channel Electrocardiograph cleared under 510(k) # **K981066**.

The SpO_2 measurement module used in the DS-8000 Series is the same as that used in the Nellcor model "OxiMax N-560 Pulse Oximeter" cleared under 510(k) # **K021090**.

The SpO_2/ SpCO/ SpMet/ SpHb measurement used in the DS-8000 Series is the same as that used in the Masimo model "Masimo Rainbow SET® RADICAL 7R CO-Oximeter" cleared under 510(k) # **K100428**.

The CO_2 measurement module used in the DS-8000 Series is the same as that used in the Oridion model "Capnostream20" cleared under 510(k) # **K094012**.

The CO_2 measurement sensor connected to the DS-8000 Series is the same as the Respironics model "Capnostat 5 Mainstream CO_2 Sensor" cleared under 510(k) # **K042601**.

The multigas measurement module used in the DS-8000 Series is the same as the sidestream multigas analyzer, which is manufactured by ARTEMA Medical AB, used in the Mindray model "PM-9000 Express Patient Monitor" cleared under 510(k) # **K053234**.

510(k) Summary
Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)

Description:

The Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor is meant to acquire and monitor physiological signals from patients. The system is design to be used in ICU, CCU, OR, ER, or Recovery areas of the hospital or clinic. Patient ages from neonates to adults can all be monitored. Waveforms, numeric and trend data from these patients are available to the clinician on the systems display or may be printed on the system's recorder.

The model DS-8500 is a modular monitor. The system consists of the main control unit (model: DSC-8510/DSC-8530), the display unit (model: LC-8019T/LC-8019TC/LC-8015T/LC-8015TC), the Super Unit (model: HS-8312N/HS-8312M), the HS Adapter (model: HSA-80) for the Super Unit attachment, the Input Box (model: IB-8004), the Expansion Modules (model: HM-800/HG-810/HG-820/HP-800) that plug into the input box, the Expansion Units (model:MGU-801P/MGU-802/ MGU-803/MGU-811P/MGU-812/MGU-813/HR-800), CO_2 Gas Unit (model: HCP-800), and Gas Unit I/F (model: HPD-800). The main body of the system in designed so it can be remotely located from the display unit, the Super Unit, the Recorder Unit, and the Input Box.

There are two (2) types of the main units depending on the built-in display board configuration as follows.

DSC-8510: External Monitor Output (1ch)
DSC-8530: External Monitor Output (1ch), Extended Display Monitor Output (2ch), LAN (TCP/IP) IF (1ch)

There are four (4) types of the display units depending on the display size and filter as follows.

LC-8019T: 19 inches
LC-8019TC: 19 inches with Circular Polarizing Filter
LC-8015T: 15 inches
LC-8015TC: 15 inches with Circular Polarizing Filter

The display unit contains a 15/19 inches diagonal, active matrix TFT color display and a clear touch screen. The 15/19"display is capable of presenting up to 20/28 waveforms.

The user interfaces, the touch screen panel, is located on the front of the display unit. The transparent area covering the display has a variable number of keys that are activated by software and depend on the display/function that the user selects. And there are five (5) fixed keys (Alarm Silence, NIBP Start/Stop, Home, Menu, and Prev. Disp.) and Jog Dial on the right side of the front of the display unit. The infrared

510(k) Summary
Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)

remote-control command is also available (optional). The right side of the display unit contains two (2) Mouse/Keyboard Connection Connectors (PS/2 port).

The model DS-8200 is a modular monitor. The system consists of the Display Unit (model: LC-8210), the HS Adapter (model: HSB-80), the Base Unit (model: BS-8210), the Super Unit (model: HS-8312N/HS-8312M), CO_2 Gas Unit (model: HCP-800), Gas Unit I/F (model: HPD-800), and the Recorder Unit (model: HR-800).

The Display Unit (LC-8210) contains a 10.2 inches diagonal, active matrix TFT color display and a clear touch screen. The 10.2"display is capable of presenting up to 14 waveforms. It also contains the Standby Switch, the Power Supply Indicator, and the Battery Charge LED on the bottom left of the front side, an alarm indicator, which alerts to alarm conditions, on the top, Telemeter Module (HLX) Insertion Slot (with the cover), one (1) CF Card Slot, one (1) CF Card Access Indicator, one (1) SD Card Slot, and one (1) SD Card Access Indicator on the right side, one (1) Display Unit Extension Cable Connector on the left side, and interface connector to the HS Adapter (HSB-80) on the rear side.

The HS Adapter (HSB-80) contains one (1) Display Unit Connector, the Display Unit Extension Cable Connector, the Operation Mode Change Switch (reserved), and the Battery Charge LED on the front side, one (1) module-LAN Connector on the right side, and the Super Unit Connector and the Battery Insertion Slot (with the cover) on the left side.

The Base Unit (BS-8210) contains the Power Supply Indicator, the Battery Charge LED, the Battery Insertion Slot (with the cover), and one (1) Serial Connector (COM1) on the front side, the AC Mains Input Connector, one (1) Serial Connector (COM2), one (1) External Monitor Connector, two (2) Status Input/Output Connectors, and one (1) DS-LAN Connector on the rear side, one (1) U-LINK Connector on the left side, and the HS Adapter Connector on the top.

The user interfaces, the touch screen panel, is located on the front of the display unit. The transparent area covering the display has a variable number of keys that are activated by software and depend on the display/function that the user selects. The infrared remote-control command is also available (optional). An option battery, which is built in to the Base Unit (BS-8210) and/or HS Adapter (HSB-80), operation allows a patient to continue to be monitored during intra-hospital transport.

The HS-8312N/HS-8312M Super Unit provides monitoring of ECG (Up to 12lead), heart rate, respiration (RESP), non-invasive blood pressure (NIBP), pulse rate (PR), arterial oxygen saturation (SpO_2), plethysmograph, and up to six (6) channels of parameters in any combination of invasive blood pressure (IBP), temperature (TEMP), and cardiac output (CO) using three (3) multiparameter connectors. In addition, the HS-8312M provides monitoring of carboxyhemoglobin saturation (SpCO),

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Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)

methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb). The NIBP measurement for the HS-8312N/M utilizes the NIBP module that is the exact same technology and algorithm as approved in the Fukuda Denshi Model DS-7000 Series Patient Monitor and provides the 510(k) #**K083697**. And the 12-Lead ECG monitoring provides the 12-Lead ECG analysis function using the 12-Lead ECG analysis software module that is the same as that used in the Fukuda Denshi CardioMax model FX-4010 Multi Channel Electrocardiograph, 510(k) #**K981066**. The HS-8312N for SpO_2 measurement utilizes a technology of an OxiMax N-560 Pulse Oximeter manufactured by Nellcor and previously cleared under 510(k) #**K021090**. The HS-8312M for SpO_2, SpCO, SpMet, and SpHb measurement utilizes a technology of a Masimo Rainbow SET® RADICAL 7R CO-Oximeter manufactured by Masimo and previously cleared under 510(k) # **K100428**. The NIBP Start /Stop Key with indicator, which lights during NIBP measuring, BP Zero Balance Key with indicator, which lights during BP zero balancing, Alarm Silence Key with indicator, which lights during the alarm silence condition, and Power Supply Indicator are located on the top of the front panel. And all parameter connectors are on the front panel and are labeled. The left side of the unit contains the Analog Output Connector that outputs the ECG and BP waveforms, including the QRS SYNC output signal. To connect the Super Unit to the Main Unit, the HSA-80 HS Adapter (for DS-8500)/HSB-80 HS Adapter (for DS-8200) is required.

The HCP-800 CO_2 Gas Unit or HPD-800 Gas Unit I/F provides monitoring of carbon dioxide concentration (CO_2) by connecting to the AUX Connector on the front of the Super Unit. The CO_2 Gas Unit (HCP-800) that utilizes Oridion Medical 1987 Ltd. technology "Microstream®" and previously cleared under 510(k) #**K094012.** The Gas Unit I/F (HPD-800) allows to connect the Capnostat 5 Mainstream CO_2 Sensor, 510(k) #**K042601**, manufactured by Respironics Novametrix, LLC. to the Super Unit with serial communication protocol for CO_2 monitoring.

The HM-800 Multi Module provides monitoring of up to four (4) channels of parameters in any combination of invasive blood pressure (IBP), temperature (TEMP), and cardiac output (CO) using two (2) multiparameter connectors, which are on the front panel and are labeled. The Power Supply Indicator and BP Zero Balance Key with indicator, which lights during BP zero balancing, are located on the top of the front panel.

The HG-810/MG-820 SpO_2 Module provides monitoring of arterial oxygen saturation (SpO_2), plethysmograph, and pulse rate (PR). The HG-810 also provides monitoring of carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb). The MG-810 utilizes a technology of a Masimo Rainbow SET® RADICAL 7R CO-Oximeter manufactured by Masimo and previously cleared under 510(k) # **K100428**. The HG-820 utilizes a technology of an OxiMax N-560 Pulse Oximeter manufactured by Nellcor and previously cleared under 510(k) # **K021090**. And the SpO_2 connector is on the front panel and is labeled and

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the Power Supply Indicator is located on the top of the front panel. In addition, in conjunction with the Super Unit, it provides monitoring of two (2) different sites of arterial oxygen saturation (SpO_2). In case of HG-810 in conjunction with the HS-8312M, the monitoring of two (2) different sites of carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb) is also available.

The HP-800 Multiport Module contains two (2) Status Input/Output Connectors for serial communications with the external device and one (1) Analog Input Connector, which 2 channels of inputs are available, to input analog signal from the external device. All connectors related to connection with the external devices are on the front panel and are labeled and the Power Supply Indicator is located on the top of the front panel.

The IB-8004 Input Box provides the expansion monitoring by plugging the Expansion Modules, such as HM-800, HG-810/MG-820, and HP-800, into. There are four (4) slots for Expansion Module plug-in. Within one (1) DS-8500 system, the connectable number of Input Box is up to two (2), so the plugging of up to eight (8) Expansion Modules is available.

The MGU-800 series (MGU-801P/MGU-802/MGU-803)/ 810 series (MGU-811P/MGU-812/MGU-813) Multigas Unit provides monitoring of carbon dioxide concentration (CO_2), nitrous oxide concentration (N_2O), oxygen concentration (O_2), and anesthetic agent concentration (AG). It utilizes a technology of the sidestream multigas analyzer manufactured by ARTEMA Medical AB. and previously cleared under 510(k) # **K053234** by Mindray. Depending on the following model type of the Multigas Unit, the measurable gas parameters are as follows.

MGU-801P/MGU-811P:	CO_2, N_2O, O_2, and AG
MGU-802/MGU-812:	CO_2, N_2O, and AG
MGU-803/MGU-813:	CO_2, and N_2O

In addition, the MGU-810 series (MGU-811P/MGU-812/MGU-813) provides monitoring of spirometry that utilizes the respiratory mechanics analyzer and flow sensor, manufactured by ARTEMA Medical AB, which is similar to a technology previously cleared under 510(k) # **K062754** by Datascope. All connectors related to measurement are on the front panel and are labeled and the Power Supply Indicator is located on the top of the front panel.

The HR-800 Recorder Unit, a dot matrix thermal printer, provides hard copy recording s of all monitored parameters and can print up to three (3) waveforms simultaneously. On the top of the front panel, the Power Supply Indicator, Print Key with indicator, which lights during printing, and Paper Feed Key with indicator, which

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Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)

lights during paper feeding, are located. The Open/Close Lever to open/close the paper holder is located on the right upper part of the front of the unit.

Additional standard features include the DS-LAN connection, which is a proprietary network system based on an Ethernet LAN (**K970585**), through either a built in Ethernet LAN or external telemetry transmitter (the Fukuda Denshi DS-5000 series telemetry model HLX-501/561, **K980728**) connection for connection to the Fukuda Denshi Central Station Monitors.

Physical Description

The physical dimensions of the DS-8500 main unit with 19" display unit (LC-8019T/8019TC) and stand (model: OAO-44A, Optional) attached are 422mm high by 468mm wide by 202mm deep. The physical dimensions of the main unit with 15" display unit (LC-8015T/8015TC) and stand (model: OAO-44A, Optional) attached are 362mm high by 395mm wide by 202mm deep. The 19" display unit by itself measures 371mm high by 468mm wide by 56mm deep. The 15" display unit by itself measures 297mm high by 395mm wide by 50mm deep.

The physical dimensions of the DS-8200 system with the Display Unit (LC-8210), the HS Adapter (HSB-80), the Base Unit (BS-8210), and the Super Unit (HS-8312N/HS-8312M) are 302mm high by 270mm wide by 201mm deep. The Display Unit (LC-8210) by itself measures 210mm high by 270mm wide by 66mm deep. The HS Adapter (HSB-80) by itself measures 210mm high by 230mm wide by 135mm deep. The Base Unit (BS-8210) by itself measures 180mm high by 270mm wide by 92mm deep.

The Super Unit (HS-8312N/HS-8312M) measures 100mm high by 85mm wide by 200mm deep. The HS Adapter (HSA-80) measures 68mm high by 85mm wide by 188mm deep. The Input Box (IB-8004) measures 129mm high by 184mm wide by 164mm deep. The Expansion Module (HM-800/HG-810/ HG-820/HP-800) measures 100mm high by 40mm wide by 135mm deep. The Expansion Unit (MGU-801P/MGU-802/MGU-803/MGU-811P/MGU-812/ MGU-813) measures 109mm high by 125mm wide by 200mm deep and HR-800 measures 109mm high by 87mm wide by 100mm deep.

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Statement of Intended Use:

The Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor provides a simple and reliable method to display and document the continuous hemodynamic, cardiovascular observations that are typically required of critically ill patients. The target populations of the system are adult, pediatric, and neonatal patients, who may be located in a hospitals ICU, CCU, OR, ER, recovery or other critical care area, with the exception of the ST segment, arrhythmia analysis, and SpHb for which the target populations are adult and pediatric only excluding neonates. The DS-8000 Series monitor can also be used to follow patients whose treatment requires close observation of specific physiological parameters. These patients may be in a clinic or other healthcare environment under the care of a physician.

The availability of DS-LAN connection, through either a built in Ethernet LAN or external telemetry transmitter, allows remote monitoring when combined with Fukuda Denshi Central Station Monitors.

Parameters such as ECG, heart rate, respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO_2), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and total hemoglobin concentration (SpHb), plethysmograph, temperature, invasive blood pressure (IBP), cardiac output, carbon dioxide concentration (CO_2), nitrous oxide concentration (N_2O), oxygen concentration (O_2), anesthetic agent concentration (AG), and Spirometry may be monitored individually or in any grouping required by the clinician.

The Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor is not recommended for home use, when it has not been ordered by a physician.

Technological Characteristics:

The DS-8000 Series incorporates the identical technology as the predicate devices. The device provides a means with interfacing with a patient, collecting parameter specific physiological data and processing the data for alarm generation, display of numeric values and waveforms at bedside or at a central monitoring station.

The technology characteristics of the DS-8000 Series do not affect the safety or efficacy of the device. Any safety issues raised by a software control medical device are either the same issues already addressed by the predicate devices or are addressed the system hazard analysis, or in the system validation.

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Testing:

The Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor has been subjected to extensive safety, environmental and performance testing.
Final testing for the device included various performance test for the device designed to insure that all functional and performance specifications were met. Additionally the device was host tested at the previously noted OEM engineering test facility to insure that performance and functional specifications for their supplied module were met.

The DS-8000 Series has also been tested to assure compliance to the requirement of various published standards including the following:

General safety standards

- IEC 60601-1: 1988+A1: 1991+A2: 1995
- IEC 60601-1-1: 2000
- IEC 62304: 2006
- IEC 62366: 2007
- IEC 60601-1-8: 2006
- ISO 14971: 2007

Individual standards

- ANSI/AAMI EC11: 1991/(R)2007
- ANSI/AAMI EC13: 2002/(R)2007
- ANSI/AAMI EC53: 1995/(R)2008
- ANSI/AAMI EC57: 1998/(R)2008
- ANSI/AAMI SP10: 2002/(R)2008 +A1: 2003/(R)2008+A2: 2006/(R)2008
- IEC 60601-2-25: 1993+A1: 1999
- IEC 60601-2-27: 2005
- IEC 60601-2-30: 1999
- IEC 60601-2-34: 2000
- IEC 60601-2-49: 2001
- IEC 60601-2-51: 2003
- EN 12470-4: 2000+A1: 2009
- EN 980: 2008
- ISO 21647: 2004, including Cor 1: 2005
- ISO 9919: 2005

EMC standards

- IEC 60601-1-2 Ed.3.0: 2007

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Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor (Model: DS-8500/8200)

Conclusion:

In conclusion, drawing from laboratory testing, validation, and risk analysis, the Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor demonstrates that this device is as safe and effective and performs as well as the legally marketed predicate devices, the Fukuda Denshi DS-5300 Patient Monitor 510(k) # **K964187**, the Fukuda Denshi DS-7000 Series Patient Monitor (Model: DS-7000/7000M/7210/7210M) 510(k) # **K083697,** the Fukuda Denshi CardioMax model FX-4010 Multi Channel Electrocardiograph cleared under 510(k) # **K981066** (12-Lead ECG analysis portion), the Nellcor model "OxiMax N-560 Pulse Oximeter" 510(k) # **K021090** (SpO_2 portion), the Masimo model "Masimo Rainbow SET® RADICAL 7R CO-Oximeter" 510(k) # **K100428** (SpO_2/ SpCO/ SpMet/ SpHb portion), the Oridion Medical 1987 Ltd. model "Capnostream20" 510(k) # **K094012** (CO_2 portion), the Respironics model "Capnostat 5 Mainstream CO_2 Sensor"510(k) # **K042601** (CO_2 portion), the Mindray model "PM-9000 Express Patient Monitor" 510(k) # **K053234** (Multigas portion), and Datascope model "Gas Module SE" 510(k) # **K062754** (Spirometry portion).